

May 7, 2021

**VIA ECF**

Honorable Edward S. Kiel, U.S.M.J.  
United States District Court, District of New Jersey  
United States Post Office & Courthouse  
Federal Square, Courtroom 8  
Newark, New Jersey 07101

Re: ***Plaintiffs' Request for Limited Discovery and Opposition to Defendants' Request for a Stay Pending Resolution of Motions to Dismiss***  
*United States ex rel. Silbersher v. Janssen Biotech, Inc.*,  
No. 19-cv-12107-KM-ESK  
*Louisiana Health Service & Indemnity Co. v. Janssen Biotech, Inc.*,  
No. 19-cv-14146-KM-ESK  
*KPH Healthcare Services, Inc. v. Janssen Biotech, Inc.*,  
No. 20-cv-05901-KM-ESK

Dear Judge Kiel:

We represent Plaintiffs in the above-referenced cases. Pursuant to Your Honor's March 16, 2021 Order, we provide this letter in further support of our request to allow limited discovery on core issues to begin, and in opposition to Defendants' motion for a stay pending resolution of the motions to dismiss.

The Federal Rules of Civil Procedure ("Rules") seek to "secure the just, speedy, and inexpensive determination of every action."<sup>1</sup> Plaintiffs filed the first complaint in these coordinated cases three and a half years ago, yet the parties have engaged in no discovery whatsoever. At this stage, although the Rules permit full discovery, Plaintiffs propose that the parties proceed with a narrow set of discovery tasks intended to:

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<sup>1</sup> Fed. R. Civ. P. 1.

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(1) lay the groundwork for full discovery to efficiently proceed once the motions to dismiss are decided; and (2) allow for the preservation and production of key documents that are readily available and identifiable.

Defendants' position that the parties should remain idle while the Court decides three separate motions to dismiss is contrary to the Rules and cannot be justified. The law is clear: the pendency of a motion to dismiss does not satisfy the good cause requirement under Rule 26(c)(1). Defendants' belief in their pending motions changes nothing. Courts routinely uphold the type of well-pled claims asserted in Plaintiffs' complaints; these cases are no exception. The chances that *all* claims in *all three* cases will be dismissed is vanishingly thin. Even if the motions somehow narrow the cases, the threshold discovery Plaintiffs currently seek will *still* be necessary. The Court should allow the discovery Plaintiffs propose and deny Defendants' motion for a stay.

## **I. Background**

In December 2017, the first complaint in these coordinated actions was filed under the False Claims Act.<sup>2</sup> In April 2019, End-Payor Plaintiffs filed the first antitrust

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<sup>2</sup> *United States ex rel. Silbersher v. Janssen Biotech, Inc.*, No. 19-cv-12107-KM-ESK (D.N.J. Dec. 21, 2017), ECF No. 1 (“*qui tam*” or “*QT*”).

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class action,<sup>3</sup> followed by a Direct Purchaser antitrust class action in May 2020.<sup>4</sup> All three cases center upon the enforcement of supposed patent rights through sham litigation filed by Defendants, which Plaintiffs allege suppressed the entry of generic competition, forcing purchasers to pay millions of dollars in overcharges.<sup>5</sup>

Plaintiffs propose the following initial discovery:<sup>6</sup>

Date	Event
June 14, 2021 <sup>7</sup>	Parties serve Rule 26(a) disclosures.
June 21, 2021	Parties submit proposed joint stipulated (1) confidentiality order and (2) ESI protocol for Court approval. <sup>8</sup>  For any section(s) of the order and/or protocol where the parties cannot come to terms, the parties shall lay out the competing proposed language and no more than two paragraphs per side advocating for their position.

<sup>3</sup> *Louisiana Health Service & Indemnity Co. v. Janssen Biotech, Inc.*, No. 19-cv-14146-KM-ESK (D.N.J. Apr. 18, 2019), ECF No. 1 (“End-Payor Plaintiffs” or “Louisiana”).

<sup>4</sup> *KPH Healthcare Services, Inc. v. Janssen Biotech, Inc.*, No. 20-cv-05901-KM-ESK (D.N.J. May 14, 2020), ECF No. 1 (“Direct Purchaser Plaintiffs”).

<sup>5</sup> Plaintiffs provided a detailed overview of the complaints in opposing Defendants’ motions and explained the procedural history in the parties’ joint status letter submission. *See Louisiana*, ECF Nos. 150, 158. Those facts are not repeated herein.

<sup>6</sup> Since the filing of the joint status letter, Plaintiffs further refined the discovery we seek at this juncture. Defendants declined to discuss any proposal. *See Ex. A*, Apr. 12, 2021 Email from J. Greenbaum to L. Barnes.

<sup>7</sup> Motion to dismiss briefing in both antitrust class actions will be complete by June 7, 2021. The third round of motion to dismiss briefing in the *qui tam* action will be complete by July 5, 2021.

<sup>8</sup> On March 5, 2021, Plaintiffs provided Defendants with a draft confidentiality order and ESI Protocol.

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July 21, 2021	Production of the following documents: (1) documents from the underlying patent litigation, Patent and Trademark Office (“PTO”) and Patent and Trademark Appeal Board (“PTAB”) proceeding, including (a) discovery documents and privilege logs, (b) transcripts of court proceedings and depositions, (c) expert reports, and (d) unredacted copies of sealed or redacted pleadings; (2) patent prosecution files as to certain relevant patents (to the extent not subsumed in (1)(a) above); and (3) documents concerning the relevant patent filings, such as memoranda and presentations relating to any response to or request for information from the Patent Office (to the extent not subsumed in 1(a) above).
August 27, 2021	Parties serve initial Requests for Production.  Unless otherwise ordered by the Court, the parties shall not be required to provide answers until thirty days after the Court rules on the currently pending motions to dismiss.
Within 20 days of rulings on Rule 12 motions	Parties submit a Rule 26(f) report, <sup>9</sup> including joint or competing schedules for the remainder of the case through trial.

## II. Legal Standard

Rule 26(c) allows a court to stay discovery only upon “good cause” shown. The filing of a dispositive motion does not constitute “good cause.” *Gerald Chamales Corp. v. Oki Data Ams., Inc.*, 247 F.R.D. 453, 454 (D.N.J. 2007). The party requesting the stay bears the burden to “make out a clear case of hardship or inequity in being required to go forward.” *Landis v. N. Am. Co.*, 299 U.S. 248, 255 (1936). Courts weigh a number

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<sup>9</sup> To the extent Defendants argue that discovery should not commence until the Court holds a Rule 16 conference and/or the parties submit a Rule 26(f) report, Plaintiffs are willing to do both immediately.

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of factors, including: “(1) whether a stay would unduly prejudice or present a clear tactical disadvantage to the non-moving party; (2) whether denial of the stay would create a ‘clear case of hardship or inequity’; (3) whether a stay would simplify the issues and the trial of the case; and (4) whether discovery is complete and/or a trial date has been set.” *See Morgan v. Quest Diagnostics, Inc.*, 2020 WL 7183503, at \*1 (D.N.J. June 8, 2020) (Kiel, J.) (internal citation omitted). Courts must be “mindful that the stay of a civil proceeding constitutes ‘an extraordinary remedy.’” *Id.* (internal citation omitted).

### **III. The Court should grant Plaintiffs’ request to begin core discovery.**

#### **A. Defendants’ motions to dismiss will not resolve this case.**

Defendants rest their stay argument only on their pending motions to dismiss. Setting aside that a motion to dismiss does not satisfy the good cause requirement, courts in this Circuit, and elsewhere, consistently refuse to dismiss sham litigation cases on Rule 12 motions.<sup>10</sup> Over the past two decades, courts have dismissed virtually none of the dozens of generic suppression cases in their entirety; and where they have, the claims have almost always been fully revived on appeal. *See, e.g., In re Lipitor*

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<sup>10</sup> *See, e.g., Indivior Inc. v. Dr. Reddy’s Lab’ys. S.A.*, 2020 WL 4932547, at \*10 (D.N.J. Aug. 24, 2020) (refusing to dismiss sham litigation counterclaims because resolution turned on “issues of reasonableness and intent-issues which are premature” at the motion-to-dismiss stage); *see also Louisiana*, ECF 158 at 9-10, nn.17-18.

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*Antitrust Litig.*, 855 F.3d 126 (3d Cir. 2017), *as amended* Apr. 19, 2017.<sup>11</sup> Similarly, a recent *qui tam* decision, described by Defendants as a “nearly identical FCA action[],”<sup>12</sup> denied a motion to dismiss and rejected many of the same arguments Defendants raise here.<sup>13</sup> These cases are no exception and Defendants’ belief in the viability of their motions does not change this reality.

Plaintiffs’ complaints contain detailed and well-pled allegations demonstrating that Defendants knew that the ’438 patent would be invalidated, yet they filed litigation against generic manufacturers to stave off competition. Plaintiffs’ oppositions to Defendants’ motions to dismiss<sup>14</sup> aptly demonstrate that there is no basis in fact or law to dismiss the claims in *all three* of these cases.<sup>15</sup>

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<sup>11</sup> In the parties’ joint status report, Defendants could only identify three cases in the past two decades that have been dismissed, one of which, *In re Humira (Adalimumab) Antitrust Litigation*, 465 F. Supp. 3d 811 (N.D. Ill. 2020), *appeal argued*, No. 20-2402 (7th Cir. Feb. 25, 2021)—is on appeal and is not even a generic suppression case.

<sup>12</sup> See *QT*, ECF No. 79-1 at 1 & n.2.

<sup>13</sup> See *Silbersher v. Allergan Inc.*, 2020 WL 7319407 (N.D. Cal. Dec. 11, 2020), *appeal pending* No. 21-15420 (9th Cir. Mar. 9, 2021). This well-reasoned, 76-page decision, also declined to follow the holding of *United States ex rel. Silbersher v. Valeant Pharmaceutical International, Inc.*, 445 F. Supp. 3d 393 (N.D. Cal. 2020), *appeals pending* Nos. 20-16176, 20-16256 (9th Cir. June 16, 2020), dismissing a similar *qui tam* on public disclosure grounds (*i.e.*, not on the merits). *Allergan* confirms the viability of the merits, and *Valeant* did not reach the merits.

<sup>14</sup> Relator’s third opposition to Defendants’ Rule 12 motion will be filed on May 20, 2021. Relator’s opposition to Defendants’ prior Rule 12 motion was administratively terminated and can be found at *QT*, ECF No. 89.

<sup>15</sup> Defendants’ attempt to send the Direct Purchaser Plaintiffs case, one of three cases

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**B. The outcome of Defendants’ Rule 12 motions will not alter the need for the discovery Plaintiffs currently seek.**

Even in the unlikely event that the motions to dismiss somehow narrow the parties or claims, Defendants have not and cannot articulate how such a ruling would impact the scope or content of the limited discovery Plaintiffs initially seek. For example, nothing about the outcome of Defendants’ motions to dismiss will alter the confidentiality order or ESI protocol. The same is true of initial disclosures. Indeed, requiring the parties to engage with their clients early about the location of documents and the identity of witnesses likely to have discoverable information is critical to ensuring that each side preserves all potentially relevant information. This is particularly important here, where the conduct at issue began as far back as 2007 and spans over a decade. Initial disclosures will also help kickstart post-motion to dismiss discussions regarding custodians and deponents. Serving document requests, but not requiring either side to produce responses and objections until after the motions to dismiss are decided accomplishes the same objective—allowing each side to secure an understanding of the types of documents and custodial files that are likely to be sought and must be preserved. Likewise, Plaintiffs seek a streamlined set of core documents that are readily identifiable and available. Indeed, Defendants confirmed that “these

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before the Court, to arbitration does not alter this analysis.



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documents have been secured and preserved.”<sup>16</sup> There is no real dispute that documents relating to the prosecution of the patents before the PTO and PTAB as well as all documents from the underlying litigation are centrally relevant to this litigation and will need to be produced in their entirety. This is precisely the type of “discovery [that] will serve to educate plaintiffs concerning the most important individuals and issues,” and help lay the groundwork for future discussions regarding custodians and potential deponents.<sup>17</sup> For these reasons, courts in generic suppression cases routinely allow this type of discovery while motions to dismiss are pending.<sup>18</sup>

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<sup>16</sup> See *Louisiana*, ECF No. 150 at 7.

<sup>17</sup> *Udeen v. Subaru of Am., Inc.*, 378 F. Supp. 3d 330, 333 (D.N.J. 2019). In our experience, these productions also expose gaps that may need to be remedied by procuring documents from sources other than Defendants. Identifying these gaps early is critical from both an efficiency and evidentiary standpoint.

<sup>18</sup> See, e.g., *In re Lipitor Antitrust Litig.*, No. 12-cv-2389 (D.N.J. Oct. 19, 2012), ECF No. 197 (allowing “limited discovery [that] focuses on documents and written materials that have been produced previously in patent litigation or other litigation, or documents submitted to the Patent and Trademark Offices and the Food and Drug Administration”); *In re: Niaspan Antitrust Litig.*, No. 13-md-2460 (E.D. Pa. Feb. 19, 2014), ECF No. 61 (allowing discovery prior to resolution of motions to dismiss, including initial disclosures, protective order, production of New Drug Applications, court pleadings, transcripts, expert reports and transaction-level data); *In re: EpiPen (Epinephrine Injection, USP) Mktg., Sales Pracs. & Antitrust Litig.*, No. 17-md-2785 (D. Kan. Oct. 5, 13, 2017), ECF Nos. 54, 58 (allowing discovery other than depositions to proceed before resolution of motion to dismiss); *Staley v. Gilead Scis., Inc.*, No. 19-cv-2573 (N.D. Cal. Sept. 9, 2019), ECF No. 163 (allowing focused discovery while motions to dismiss were pending); *In re Novartis & Par Antitrust Litig.*, No. 18-cv-4361 (S.D.N.Y. Aug. 3, 2018), ECF No. 59 (allowing initial disclosures and fact discovery prior to ruling on motions to dismiss).



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In short, Plaintiffs' approach "is fair to all parties. On the one hand plaintiffs can immediately proceed to obtain plainly relevant and important core discovery. On the other hand, the 'floodgates' of discovery will not open until defendants' motion is decided and the issues to be litigated are joined." *Udeen*, 378 F. Supp. 3d at 333-34.

**C. Delaying discovery will prejudice Plaintiffs.**

A delay of discovery until the Court decides Rule 12 motions prejudices Plaintiffs. As one court in this District recently found, "[g]iven the extensive briefing on defendants' motion and the expected time it will take for the motion to be decided, the case will be in suspense for months if defendants' request is granted. Having filed their complaint plaintiffs have a right to move forward." *Udeen*, 378 F. Supp. 3d at 333. This Court recently acknowledged that "given the judicial emergency in this District, the resolution of the Motion to Dismiss may be many months away." *Morgan*, 2020 WL 7183503, at \*2. That finding applies with even more force here where *years* have passed since these actions were first filed, the Court has *three* motions to dismiss to decide, and the parties have not been able to engage in any discovery to date. "The longer the case languishes the greater that relevant evidence may be lost or destroyed." *Udeen*, 378 F. Supp. 3d at 333 ("[D]elaying trial would increase the danger of prejudice resulting from the loss of evidence including the inability of witnesses to recall specific facts, or the possible death of a party." (quoting *Clinton v. Jones*, 520 U.S. 681, 707-

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08 (1997))). The delay also provides a clear tactical advantage to Defendants, who have relied extensively on cherry-picked statements from a redacted transcript in pursuing dismissal of Plaintiffs' claims.<sup>19</sup> The Court should not sanction such a result.

In contrast, Defendants will suffer no prejudice if discovery proceeds and certainly not the type of "clear case of hardship or inequity" that is required to procure a stay. *Landis*, 299 U.S. at 255. Defendants compiled and produced or served most, if not all, the documents Plaintiffs seek in the underlying patent litigation.<sup>20</sup> Producing the same set of documents to Plaintiffs' counsel in this case involves little additional effort or expense. Any burden or expense is proportional to the needs of this case given the relevance of the discovery Plaintiffs seek.

#### **IV. Conclusion**

Years have passed since these cases were filed. Defendants cannot satisfy the good cause standard and continuing to delay discovery while awaiting resolution of all three motions to dismiss is unnecessary and will result in prejudice to Plaintiffs. Plaintiffs respectfully request that the Court allow the parties to engage in the focused and reasonable discovery tasks set forth above.

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<sup>19</sup> See, e.g., *Louisiana*, ECF No. 155-1 at 3.

<sup>20</sup> To the extent that the Protective Order in the underlying litigation requires notice to or authorization from any third parties, it serves the interest of efficiency for Defendants to begin the process now.

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Respectfully yours,

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